IRW

Docket No.: 1268-215 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
	:	
Oded NAHLEILI	:	*Confirmation No.* 3022
	:	
U.S. Patent Application No. 10/762,583	:	Group Art Unit: 3735
	:	
Filed: January 23, 2004	:	Examiner: Ahmed M. Farah

For: A SYSTEM AND METHOD FOR PULVERIZING STONES AND SCAR REMOVAL IN SOFT TISSUES

CLAIM OF PRIORITY AND TRANSMITTAL OF CERTIFIED PRIORITY DOCUMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 35 U.S.C. 119, Applicant hereby claims, in the present application, the priority of Israel Patent Application No. 154120 filed January 24, 2003. The certified copy is submitted herewith.

Respectfully submitted,
LOWE HAUPTMAN & BERNER, LLP

Benjamin J. Hauptman
Registration No. 29,310

1700 Diagonal Road, Suite 310
Alexandria, Virginia 22314
(703) 684-1111 BJH/mps
Facsimile: (703) 518-5499
Date: May 29, 2007

מדינת ישראל
STATE OF ISRAEL

Ministry of Justice
Patent Office

משרד המשפטים
לשכת הפטנטים

This is to certify that annexed hereto is a true copy of the documents as originally deposited with the patent application of which particulars are specified on the first page of the annex.

זאת לתעודה כי רצופים בזה העתקים נכונים של המסמכים שהופקדו לכתחילה עם הבקשה לפטנט לפי הפרטים הרשומים בעמוד הראשון של הנספח.

This 16-08-2005 היום

רשם הפטנטים
Commissioner of Patents

ד"ר מאיר נועם
רשם הפטנטים, המדגמים וסימני המסחר

נתאשר
Certified

לשימוש הלשכה
For Office Use

מספר: Number	154120
תאריך: Date	24-01-2003
הוקדם/נדחה Ante/Post-dated	

חוק הפטנטים התשכ"ז -1967
PATENTS LAW, 5727-1967

בקשה לפטנט
Application for Patent

אני, (שם המבקש, מענו – ולגבי גוף מאוגד – מקום התאגדותו)
I (Name and address of applicant, and, in case of a body corporate, place of incorporation)

עודד נחליאלי
רח' גבעתי 41
אשקלון מ. 78471

Oded Nahleili
41 Givati St,
Ashkelom 78471
ISRAEL

בעל אמצאה מכח היותי הממציא ששמה הוא:
Owner, by virtue of of an invention, the title of which is:

(בעברית) (Hebrew) מערכת ושיטה לריסוק אבנים והסרת צלקות ברקמות רכות

(באנגלית) (English)

A SYSTEM AND METHOD FOR PULVERIZING STONES AND SCARE REMOVAL IN SOFT TISSUES

hereby apply for a patent to be granted to me in respect thereof. מבקש בזאת כי ינתן לי עליה פטנט.

* בקשת חלוקה - Application for Division	* בקשת פטנט מוסף Application for Patent of Addition	* דרישת דין קדימה Priority Claim		
* מבקשת פטנט from Application No.______ מס' Dated______ מיום	* לבקשה / לפטנט To Patent/Appl. No.______ מס' Dated______ מיום	מספר/סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
* יפוי כח: כללי/מיוחד – רצוף בזה / עוד יוגש P.O.A.: general / specific - attached / to be filed later - Has been filed in case______ הוגש בענין				
המען למסירת הודעות ומסמכים בישראל Address for Service in Israel ד"ר מאיר נועם עורך-דין ועורך פטנטים ת.ד. 34335 ירושלים 91342 טל. 02-6518880 פקס'. 02-6523336				
חתימת המבקש Signature of Applicant M. Noam		היום______ בחודש______ שנת______ 200 This 200 of 200		

לשימוש הלשכה
For Office Use

טופס זה, כשהוא מוטבע בחותם לשכת הפטנטים ומושלם במספר ובתאריך ההגשה, הינו אישור להגשת הבקשה שפרטיה רשומים לעיל.
This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application, the particulars of which are set out above.

* מחק את המיותר Delete whatever is inapplicable

מערכת ושיטה לריסוק אבנים והסרת צלקות ברקמות רכות

A SYSTEM AND METHOD FOR PULVERIZING STONES AND SCARE REMOVAL IN SOFT TISSUES

ממציא: עודד נחליאלי

FIELD OF THE INVENTION

The present invention relates generally to systems useful for removing hard scares and pulverizing physiological stones, and more particularly, to a system and to a method for using an Erbium or Holmium YAG laser for crushing stones in human salivary glands.

BACKGROUND OF THE INVENTION

A medical treatment of hard tissues entrapped in a cavity comprising bogy fluids is usually difficult and follows with considerable undesired side effects. Such a treatment is usually encompasses various surgical procedures, such as stone pulverizing, removing ligaments and scar tissues from the temporomandibular joint (TMJ) etc, wherein said cavity diameter is less 3 mm so the cooling of said laser system is difficult; said system comprising

TMJ syndrome and related joint diseases and disorders, are significant epidemiology: 10 million people in the USA are been treated for TMJ at any one time, wherein one of ten of those treated will need a subsequent surgery procedure. Some of those syndromes are related to the formation of relatively hard tissues entrapped in the synovial fluid adjacent to said joint. Scar tissue is one example of such a hard tissue, located inside the TMJ. Those scars can be formed by acute trauma (e.g. a car accident) or chronic trauma (e.g. clenching or grinding), synovitis, or lack of mobility. Such a hard tissue in a joint usually results in a limitation of jaw opening. Treatment requires "passive motion" physical therapy and surgery.

A recent advance in oral and maxillofacial surgery includes the delivery of laser energy through an arthroscope. This has been an extremely beneficial advancement for outpatient TMJ surgery. For the patient with adhesion/scar tissue formation or with a limited ability to open the mouth, the utilization of the Holmium laser provides a more conservative treatment approach to the TMJ than "open" joint surgery. The procedure is

done at an* ambulatory care center, with discharge within several hours of the procedure. Most patients are back to work within 4-5 days. The conservative nature of laser debridgement of adhesions is a significant enhancement to the problems of TMJ disfunction.

U.S. Pat. No. 5,582,190 to Slavin et al. teaches a holmium laser based arthroscopic method for relieving symptoms caused by temporomandibular joint disorder in a patient. Their method is based on the following fourteen steps: (a) injecting a solution of lidocaine and epinephrine into a superior joint space of a temporomandibular joint of a patient, thereby providing distention thereof; (b) making a first vertical incision anterior to the posterior aspect of the tragus of the ear of the patient; (c) making a second vertical incision anterior to the first incision and below a line from the posterior aspect of the tragus of the ear to the lateral canthus of the orbit; (d) perforating the superior joint space bluntly with a first cannula and a first blunt trocar inserted into the first vertical incision and a second cannula and a second blunt trocar inserted into the second vertical incision; (e) advancing the first and the second cannula; (f) removing the first and the second trocar; (g) placing an arthroscope through the first vertical incision, allowing direct visualization of the joint; (h) placing a switching stick through the second vertical incision; removing the second cannula; (i) providing a dual-channel cannula having a distal end, a proximal end, a first and a second channel, each extending from the proximal to the distal end; (j) inserting the dual-channel cannula over the switching stick into an anterior recess of the superior compartment of the joint; (k) removing the switching stick; (l) locking the arthroscope into the first channel of the dual-channel cannula; (m) inserting an optical fiber into the second channel of the dual-channel cannula, the optical fiber for channeling radiation from a holmium laser; and (n) performing a desired surgical procedure within the joint space. According to Slavin's invention, the first and a second 2.0 mm cannula and a first and a second blunt trocar are used.

Additional example of removing hard tissues from relative soft organs is the pulverizing of physiological stones, and more particularly, to removal of calcium stones from the

salivary ducts. The mechanism of salivary stone formation is unclear, but seems to be multi-factorial. About 1% of people suffers from salivary stones. Most stones form in the sub-mandibular gland (85%) and the remainder in the parotid (15%).

In 1961, a laser generated from crystals of yttrium-aluminum-garnet treated with 1-3% neodymium (Nd:YAG) was developed. This laser emitted energy in the near infrared (IR) spectrum at a wavelength of 1060 nm. Researchers found its high-penetration emission to be useful for vaporizing tissues and thermally coagulating large blood vessels (<3 mm). Today, the Nd:YAG laser is mainly used to ablate tattoos and tumors of the genitourinary and gastrointestinal tracts, although it has many other uses, including ophthalmic surgery, e.g., peripheral iridectomies/iridotomies, postcataract capsulotomies, and hair removal.

During the past few years, a great number of laser systems have been used clinically for various surgical applications. Increasing interest appeared in pulsed holmium lasers at 2-μm and pulsed erbium lasers operating in the 3-μm region for tissue ablation because their radiation is strongly absorbed by tissue water. The range of clinical indications for these lasers is continually expanding because of the controllable qualities of cutting, welding, and coagulating tissue and the possibility of transmitted properties make these wavelengths attractive for minimally invasive surgical treatments. On the other hand, because clinical treatments, as they arise in orthopedics, angioplasty, ophthalmology, or lithotropsy, are usually performed in a liquid environment often in a non-contact mode, it is possible that most of the laser energy is absorbed in the water and little is left for tissue ablation. However, it has been shown that the leading part of the infrared radiation (IR) laser pulse creates a water-vapor channel bridging the water-filled space between the fiber tip and the tissue surface. Because steam has, in contrast to water, a low absorption in the IR, the channel acts as a transmissive cavity for the remaining part of the laser pulse, which renders non-contact tissue ablation possible. The rapidly expanding and subsequently collapsing water-vapor channel, however, may lead to mechanical tissue damage, the extent of which exceeds the penetration of the laser light in tissue.

The elimination of stones from the body, such as kidney stones and gallstones has been known for decades. Lithotripsy is the pulverization and removal of urinary or other calculi using a lithotripter. A lithotripter fragment kidney stones with ultrasound waves. The majority of patients (85-90%) are rendered symptom free and in 30-50% of cases, the stones are completely cleared from the salivary glands. The remainder retains some stone debris. In these patients, there is a risk of new stone formation. The lithotripsy treatment can be repeated. Calculi are stones or concretions formed in bodily organs. Non-invasive microsurgery by endoscopy with a special laser. An endoscope is an instrument for visualizing the interior of a hollow organ. Erbium is a metallic element of the rare-earth group. Erbium is always found in combination with yttrium, another rare earth, and the ore is mined in the form of yttrium-aluminum-garnet (YAG). Ablation is the removal of abnormal growths or harmful substances, for example, from the body by surgery by mechanical means. Because of the extremely strong absorption of its 3µm-radiation in biological tissue, the erbium laser has become a very useful and precise tool in surgery. The resulting penetration depths are around 2-3 µm and thus offer a minimal invasive and precise ablation of tissue. Use of the Er:YAG laser for pulverizing urological stones was achieved in 2001 at the University of Texas. Holmium lasers have an advantage for transmitting a laser beam over long distances, such as to reach the kidneys. Erbium lasers are more effective for short distances.

Erbium laser frequencies are not well suited to soft tissues, but are highly effective for hard tissues, because of the ability to pulverize these hard tissues. Consequently, erbium YAG lasers are used in dentistry as substitute for the painful, noisy drill, especially for clearing the areas of tooth decay. These frequencies have no substantial effect on surrounding soft tissues, are therefore do not damage the gums, tongue, cheeks, etc.

Advances in optical instruments have made available micro-endoscopes (1mm diameter) that allow visualization of the salivary ducts. A laser beam can now be aimed directly on the stone. The technique is in its infancy but the results are encouraging with reported cure rates of 60%

A laser produces a focused beam of light of varying wavelengths. The different wavelengths affect structures by their optimal spectrum of absorption peak. The erbium YAG laser uses a 294 nm wavelength beam of light.

Because of the opportunity of very precise treatment of tissue and the low thermal damage caused by photoablation with the erbium-laser, it is applied in a broad spectrum of medical therapeutics, like ophthalmology, orthopedics and other. One concrete application is the so-called phacoemusification of the human lens in the treatment of the cataract. To remove the cloudy lens and replace it by an intra-ocular lens, an ultrasonic probe is placed in the front chamber of the eye. Using ultrasound the lens is destroyed in small pieces and aspirated by a suction unit. By using the erbium-laser this process can be made softer and with lower risks of damages caused by the heating effect of the ultrasound in the eye.

The energy in the pulse is significant because of the increase heat generated at higher energy. Laser light can be concentrated into spots, it is therefore not surprising that the laser has found applications not only in diagnosis but also in treatment and surgery.

Laser surgery has been known since the mid-1960s, when the first retinal lesions were being successfully repaired and retina detachments averted. Today, laser surgery is a vast field of activity covering gynecology, tonsils removal, drilling and cutting bone tissues (histology), gastric bleeding, removal of port wine birthmarks and tattoos (dermatology).

The advantages of the laser are the ability to reach inaccessible place, aiming accuracy, much reduced bleeding (the laser scalpel attacks fewer cells than a steel knife and evaporates them quickly), near absence of oedema, and reduction or suppression of pain. On the negative side are low cutting speeds and safety related problems.

The first published use of the pulse-dye laser was in Japan in 1996. This involved laser lithotripsy of salivary stones with 6 of 15 cases having complete fragmentation and 3 more of the 15 cases having 50% fragmentation. The use of holmium or erbium lasers for laser lithotripsy of salivary stones is unknown in the art. The idea of using erbium lasers for endoscopy was initiated in a London hospital in 2001, but not for the salivary

glands. A group in Texas has subsequently used erbium lasers for urology, and it is well known in uses as a substitute for drilling the teeth.

When used for dentistry, for example, the laser precisely removes decay and prepares the tooth without unnecessary removal of health tooth structure. In most cases, the patient won't feel any pain so there is no need for anesthetic. Also, because the laser is so accurate, it pinpoints the decayed area and generally leaves the healthy tissue alone compared to the use of a drill, which is much harder to control. Also the patient does not hear the loud whine that the drill makes. The laser is quiet with only a soft, popping sound. The laser's beam reacts with the water at the surface of the tooth, causing the decayed tissue to vaporize.

U.S. Pat. No. 6,375,651 to Grasso the third et al. introduces a medical device, which requires a suction conduit, and an energy-transmitting conduit wherein at least some of the transmitted energy is directed to the distal region of the suction conduit. The said device includes an optical apparatus for directing the energy. The device has applications in lithotripsy and tissue-removal in a patient. Ho:YAG laser was claimed to be useful for such a procedures. The inventors also suggested to be utilized lasers based on thulium (Th), Erbium:yttrium-aluminum-garnet (Er:YAG) in the 190 to 350 nm, HF, DF, CO, and CO_2 in the mid-infrared region, and excimer lasers in the ultraviolet region. Nevertheless, said patent is by no means suitable for pulverizing stones in the salivary ducts because suction is not possible in physiological conduits small as the salivary ducts, whereat maximal diameter is narrow 3 mm. It is well acknowledged that introduction of a suction in the manner defined in this patent shall irreversibly collapse the fragile salivary duct and because of that treatment of such ducts are not defined as preferred embodiments of the said invention.

U.S. Pat. No. 6,395,000 to Mitchell et al. deserted a medical laser system for ablating biological material. The system also includes an Er:YAG laser useful for various ophthalmic procedures, including capsulotomies, sclerostomies, excision of pupillary membranes, cutting of vitreous bands and iris margin. The said system is alleged bu the inventors to be also useful for a variety of urinary organ procedures such as kidney wall

modification, stone (calculi) fragmentation and removal in the kidney, gall bladder and ureter (lithotripsy), transurethral incision of the prostate, prostatectomy, ureter lesion removal, vasal tissue removal, nephrectomy, vasovasotomy and lymph node modification. Moreover, the system supposed also to be useful for opening strictures in the aorta, modifying vessels at an aneurysm, for clearing vessels (angioplasty) and for removing clots. Most surpassingly, the system as described in aforementioned Mitchell's patent was not found useful for pulverizing stones in the salivary gland ducts.

Thus, there is a need for adapting the use of cost effective, 'cool' erbium YAG lasers adapted for other hard tissues besides teeth and bladder stones in the way it pulverizing stones and calculi in the range of 1 to 4 mm, entrapped in fragile and narrow biological conduits.

SUMMARY OF THE INVENTION

Accordingly, it is a principal object of the present invention to overcome the limitations of the prior art systems, and to provide an improved system and a method for useful for relieving symptoms caused by hard tissues such as temporomandibular joint disorders and salivary gland stones in a patient.

In general, said system is an erbium yttrium-aluminum-garnet (Er:YAG) laser system useful for treating hard tissues entrapped in a cavity comprising bogy fluids, wherein said cavity diameter is less 3 mm so the cooling of said laser system is difficult. The system comprising an endoscope for visualizing the interior of the treating hard tissues by delivery of said laser beam; and an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to pulverize the treating hard tissues. The laser beam is directed to said treating hard tissues at close enough proximity and the said Er:YAG laser is effectively pulverization of said treating hard tissues in the way calculi fragments having diameter less than 2 mm are obtained.

It is in the scope of the present invention wherein the said Er:YAG laser system is especially useful for pulverizing a calculi in narrow physiological conduits. Said conduits diameter is less 3 mm. Said system comprising: an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; and an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to pulverize the calculi. The laser beam is directed to said calculi at close enough proximity and the said Er:YAG laser is effectively pulverization of said calculi in the way calculi fragments having diameter less than 2 mm are obtained. Preferably, the narrow physiological conduits are ducts of the salivary glands and further wherein the calculi is a salivary stone. According to one particulate embodiment the endoscope is a Nahlieli type sialoendoscope, and the delivery of said laser beam is provided by a rigid curved optical fiber.

It is also in the scope of the present invention wherein the said Ho:YAG laser, especially useful for pulverizing calculi. The system comprising an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; and a Ho:YAG laser device located in said endoscope, adapted to generate a laser beam in order to pulverize said calculi. The laser beam is directed to said calculi at close enough proximity. The Ho:YAG laser is effectively pulverization of said calculi in the way calculi fragments of diameter less than 2 mm are obtained. More specifically, the narrow physiological conduits are ducts of the salivary glands and further wherein the calculi is a salivary stone. According to one particulate embodiment, the endoscope is a Nahlieli type sialoendoscope, and the delivery of said laser beam is provided by a rigid, curved optical fiber.

It also in the scope of the present invention wherein the Er:YAG laser system defined above is especially useful for relieving symptoms caused by scars and other any other temporomandibular joint disorders in a patient, particularly wherein said conduits diameter is less 3 mm. Said system comprising an endoscope for visualizing the joint surroundings by delivery of said laser beam; and an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to

treat said scars. The laser beam is directed to said scars at close enough proximity. The said Er:YAG laser is effectively pulverization of said scars, in the way calculi fragments having diameter less than 2 mm are obtained. Specifically, the scars selected from hard tissues provided due to diseases or disorders of the TMJ and its surroundings.

It is second prepuce of the present invention to present a useful method for using the Er:YAG laser system according to claim 2 for pulverizing salivary stones. The method comprising the steps as follows: providing an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; providing an Er:YAG laser device to generate a laser beam in order to pulverize the salivary stones; and than providing said laser beam throughout said endoscope. The laser beam is directed at said salivary stones at close enough proximity and further wherein said Er:YAG laser is effectively pulverization of said stones in the way calculi fragments having diameter less than 2 mm are obtained. More specifically, the endoscope is a Nahlieli type sialoendoscope, and further wherein delivery of said laser beam is by a rigid, curved optical fiber. According to another preferred embodiment of the present invention a useful method is provided for using a Ho:YAG system for pulverizing salivary stones. Said method comprising the following step: providing an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; providing a Ho:YAG device to generate a laser beam in order to pulverize the salivary stones; and than providing said laser beam throughout said endoscope. The laser beam is directed at said salivary stones at close enough proximity; and further wherein said Ho:YAG laser is effectively pulverization of said stones in the way calculi fragments having diameter less than 2 mm are obtained. In one particulate embodiment of the present invention, the endoscope in use is a Nahlieli type sialoendoscope, and the delivery of said laser beam is provided by a rigid, curved optical fiber.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the inventive system and method will become more readily apparent, and may be better understood, by referring to the following detailed description of an illustrative embodiment of the present invention, taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a schematic illustration of the tempmandibular joint and

Fig. 2 is a schematic illustration of the salivary duct comprising calcium stones.

Fig. 3 is a composite schematic illustration of an exemplary erbium YAG laser system used to depict a preferred embodiment for crushing salivary gland stones, constructed in accordance with the principles of the present invention;

Fig. 4 shows laser radiation from an optical fiber of core diameter D with refractive index n_{fiber} as delivered to a generic concentrator over an incident angular range $2\theta_a$; and

Fig. 5 is a schematic illustration of two types of Nahlieli Sialoendoscope of two types.

DETAILED DESCRIPTION OF THE INVENTION

As set forth above, it is the core of the present invention to treat medically hard tissues entrapped in a cavity comprising bogy fluids, wherein said cavity diameter is less 3 mm so the cooling of said laser system is difficult.

Two examples are hereto provided, wherein the first is the treating of scars and other diseases and disorders in the temporomandibular joint (TMJ). The second is treating of calcium stones, especially those located in the mandibular salivary ducts. Those two examples and the following description which is provided below, along all chapters of the present invention, are described to enable any person skilled in the art to make use of said invention and sets forth the best modes contemplated by the inventor of carrying out this invention.

Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide the

yttrium-aluminum-garnet (Er:YAG) laser system and/or Ho:Yag laser system defined below.

Reference is made now to figure 1 presenting the TMJ (1) located in the joint of te mandibular and maxilar bones. A magnified presentation of said TNJ is presented to comprise of a connective tissue (1) and a disc: A cross section of the area shows the capsule (3), synovial membrane (4), articular cartilage (5), internal ligament (6) and external ligament (7).

Laser is an effective instrument for cutting, vaporizing adhesions and scarring of the retrodiscal tissues. Whereat Ho:YAG laser arthroscopy is successful only in 80 to 85% of patients. it has reduced the need for open joint procedures. The laser enables the operator to cut the fibrous capsule in relative hemostasis. Vaporizing the reactive synovitis, that remains after releasing gross adhesions, minimizes their reformation post operatively. The laser can then be used in the posterior synovial pouch to scarify the retrodiscal tissue to further facilitate the posterior pull on the disc.

Reference is made now to figure 2, schematically presenting the salivary glands: parotid duct (21) communicating the mouth with the accessory parotid gland (22) the parotid gland (23) and the submandibular gland (24); and the sublingual gland (25).
For endoscopic laser lithotripsy of salivary stones, it is determined that 85% of salivary stones are located in the sub-mandibular gland (24) and 15 % in the parotid (22, 23) glands. This is the area of the mouth and jaws. Most stones are composed of calcium phosphate. Typical size range is 5-20 mm. Complete fragmentation requires fragments less than 3 mm.

With reference now to Fig. 3, there is shown a composite schematic illustration of an exemplary erbium yttrium-aluminum-garnet (YAG) laser system 100 used to depict a preferred embodiment with an 8 watt erbium laser from Schwartz Electro-Optics. Exemplary laser block diagram 110 illustrates a diode pumped erbium laser. The delivery of the laser beam is preferably done with 150 and 425 micron sapphire fibers

from Saphikon having T:82%/m. The laser beam is delivered at up to 65 micro-joules, 10 Hz, thereby providing 47 joules/cm^2. For example, Er:YAG at a wavelength of 2.94 µm in the infrared (IR) spectrum, is most highly absorbed in water, and therefore while being effective for pulverizing the salivary stones, it does no substantial damage to the surrounding soft tissues of the hollow glands being treated. The heat of pulverization can be dissipated by introducing a stream of water, for example. The energy from each pulse is effective in many applications. Thus, the same laser equipment used in dentistry can be adapted for use at many of the same facilities by application of proper endoscopes for intra-glandular trearment.

The findings include that the fragmentation threshold for 3 micron stones is lower than for 2 micron stones. Ablation efficiencies are double for 3 micron stones compared to 2 micron stones. Most fragments are less than 1 mm. The fiber tip damage threshold is approximately 100 micro-joules, when the tip is lowered into contact. When contact is not made the distance from the tip to the stone is preferably increased to raise the damage threshold.

Erbium YAG laser products are presently in use by dentists for various applications. The accessory is based on a sapphire probe, which can be used with the preferred Nachlieli scope as described below, which was developed for use in aesthetic plastic surgery. The laser is applied to the salivary glands of a patient 120, and may be delivered orally 130. A typical preferred delivery apparatus uses rigid, curved optical fiber, embodied in a probe 140 having a diameter of 1mm. Insertion of an extension of probe 140 in the salivary gland is illustrated in reference block 135

For maximum collection efficiency, ray rejection at the fiber-tissue interface due to total internal reflection is avoided. The laser rays reach the absorber plane over a restricted range of half angle θ_{out} that does not exceed the critical angle for total internal reflection from Snell's law: Fig. 2 shows laser radiation 205 from an optical fiber 200 of core diameter D 210 with refractive index n_{fiber} is delivered to a generic concentrator 215 over an incident angular range 2 θ_a. For simplicity, concentrator 215 is produced from the fiber material. Rays reaching the absorber of diameter d 220 are distributed over angular range

2 θ_{out}. The tissue environment has refractive index n_{env}. At the exit aperture 230, rays that emerge are refracted and distributed over angular range 2 θ_{exit} within the tissue.

The system may be such that the endoscope is a Nahlieli type sialoendoscope, and delivery of said laser beam is by a rigid, curved optical fiber. The Nahlieli sialoendoscope, as such as the device Type 1 or 2 commercially available by Karl Storz Ltd. The said is an endoscope useful for the diagnosis and treatment of inflammatory salivary gland diseases and for minimal temporo-mandibular-joint arthroscopy (denoted in the present invention in the term 'Nahlieli type sialoendoscope'). The hereto-defined Storz's Nahlieli sialoendoscope usually comprising two separate channels, with two blunt obturators and two LUER-lock adapters, curved channel for instruments up to 3 Fr., O.D. 1.3 mm, straight channel for use with the commercially available Miniature Telescope 28620 with lateral LUER-lock adapter for irrigation, O.D. 1.3 mm, working length 4 cm, overall length 10.7 cm.

Reference is made now to Fig. 5A, presenting a side view of a Karl Storz commercially available Nahlieli sialoendoscope, comprising a handle and blunt obturator, for use with a miniature telescope diameter 2.3 mm x 1.3 mm, working length 12 cm, and an operating sheath with obturator valve. Similarly, Fig. 5B is presenting a side view of another commercially available Nahlieli sialoendoscope comprising with two separate channels, with two blunt obturators and two LUER-lock adaptors, curved channel for instruments up to 3 Fr., O.D. 1.3 mm, straight channel for use with miniature telescope with lateral LUER-lock adaptor for irrigation, O.D. 1.3 mm, working length 4 cm, overall length 10.7 cm.

It is in the scope of the present invention, wherein the laser is a YAG laser and not a dye laser, and in particularly wherein the device is a non-rigid and gradually non-rigid member, most suitable for treating the narrow and fragile salivary ducts.

Having described the invention with regard to certain specific embodiments thereof, it is to be understood that the description is not meant as a limitation, since further

modifications will now suggest themselves to those skilled in the art, and it is intended to cover such modifications as fall within the scope of the appended claims.

CLAIMS

1. An erbium yttrium-aluminum-garnet (Er:YAG) laser system useful for treating hard tissues entrapped in a cavity comprising bogy fluids, wherein said cavity diameter is less 3 mm so the cooling of said laser system is difficult; said system comprising:

   a. an endoscope for visualizing the interior of the treating hard tissues by delivery of said laser beam; and

   b. an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to pulverize the treating hard tissues;

   wherein the laser beam is directed to said treating hard tissues at close enough proximity;

   and further wherein said Er:YAG laser is effectively pulverization of said treating hard tissues in the way calculi fragments having diameter less than 2 mm are obtained.

2. The Er:YAG laser system according to claim 1, especially useful for pulverizing a calculi in narrow physiological conduits, wherein said conduits diameter is less 3 mm and said system comprising:

   c. an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; and

   d. an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to pulverize the calculi;

   wherein the laser beam is directed to said calculi at close enough proximity;

   and further wherein said Er:YAG laser is effectively pulverization of said calculi in the way calculi fragments having diameter less than 2 mm are obtained.

3. The system according to claim 2, wherein the narrow physiological conduits are ducts of the salivary glands and further wherein the calculi is a salivary stone.

4. The system according to claim 3, wherein the endoscope is a Nahlieli type sialoendoscope, and further wherein the delivery of said laser beam is by a rigid curved optical fiber.

5. The laser system according to claim 2, comprising Ho:YAG laser, especially useful for pulverizing calculi, said system comprising:

   a. an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam; and

   b. a Ho:YAG laser device located in said endoscope, adapted to generate a laser beam in order to pulverize said calculi;

   wherein the laser beam is directed to said calculi at close enough proximity; and further wherein said Ho:YAG laser is effectively pulverization of said calculi in the way calculi fragments of diameter less than 2 mm are obtained.

6. The system according to claim 5, wherein the narrow physiological conduits are ducts of the salivary glands and further wherein the calculi is a salivary stone.

7. The system according to claim 5, wherein the endoscope is a Nahlieli type sialoendoscope, and wherein delivery of said laser beam is by a rigid, curved optical fiber.

8. The Er:YAG laser system according to claim 1, especially useful for relieving symptoms caused by scars and other any other temporomandibular joint disorders in a patient, wherein said conduits diameter is less 3 mm and said system comprising:

e. an endoscope for visualizing the joint surroundings by delivery of said laser beam; and

f. an Er:YAG laser device located inside said endoscope, adapted to generate a laser beam of about 30 to 65 joules/cm^2 in order to treat said scars;

wherein the laser beam is directed to said said scars at close enough proximity;

and further wherein said Er:YAG laser is effectively pulverization of said scars, in the way calculi fragments having diameter less than 2 mm are obtained.

9. The Er:YAG laser system according to claim 8, wherein the scars selected from hard tissues provided due to diseases or disorders of the TMJ and its surroundings.

10. A method for using the Er:YAG laser system according to claim 2 for pulverizing salivary stones, said method comprising:

a. providing an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam,

b. providing an Er:YAG laser device to generate a laser beam in order to pulverize the salivary stones; and

c. providing said laser beam throughout said endoscope;

wherein the laser beam is directed at said salivary stones at close enough proximity and further wherein said Er:YAG laser is effectively pulverization of said stones in the way calculi fragments having diameter less than 2 mm are obtained.

11. The method according to claim 10, wherein the endoscope is a Nahlieli type sialoendoscope, and further wherein delivery of said laser beam is by a rigid, curved optical fiber.

12. A method for using a Ho:YAG system according to claim 5 for pulverizing salivary stones, said method comprising:

a. providing an endoscope for visualizing the interior of the salivary glands by delivery of said laser beam,

b. providing a Ho:YAG device to generate a laser beam in order to pulverize the salivary stones;

c. providing said laser beam throughout said endoscope; and

wherein the laser beam is directed at said salivary stones at close enough proximity; and further wherein said Ho:YAG laser is effectively pulverization of said stones in the way calculi fragments having diameter less than 2 ? m are obtained.

10. The method according to claim 9, wherein the endoscope is a Nahlieli type sialoendoscope, and wherein delivery of said laser beam is by a rigid, curved optical fiber.

Dr. MEIR NOAM
ADVOCATE & PATENT ATTORNEY
P.O.B. 34335, Jerusalem
TEL. (972) 2-6518880

FIGURE 1

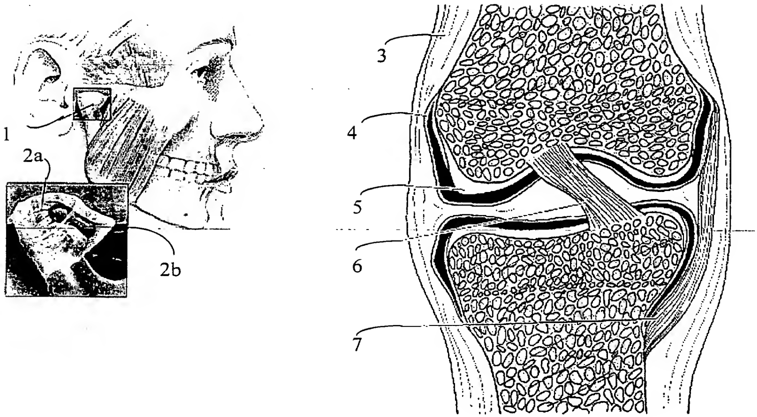


FIGURE 2

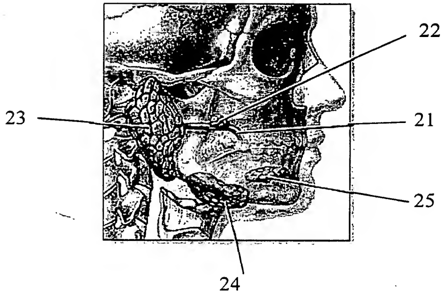


FIGURE 3

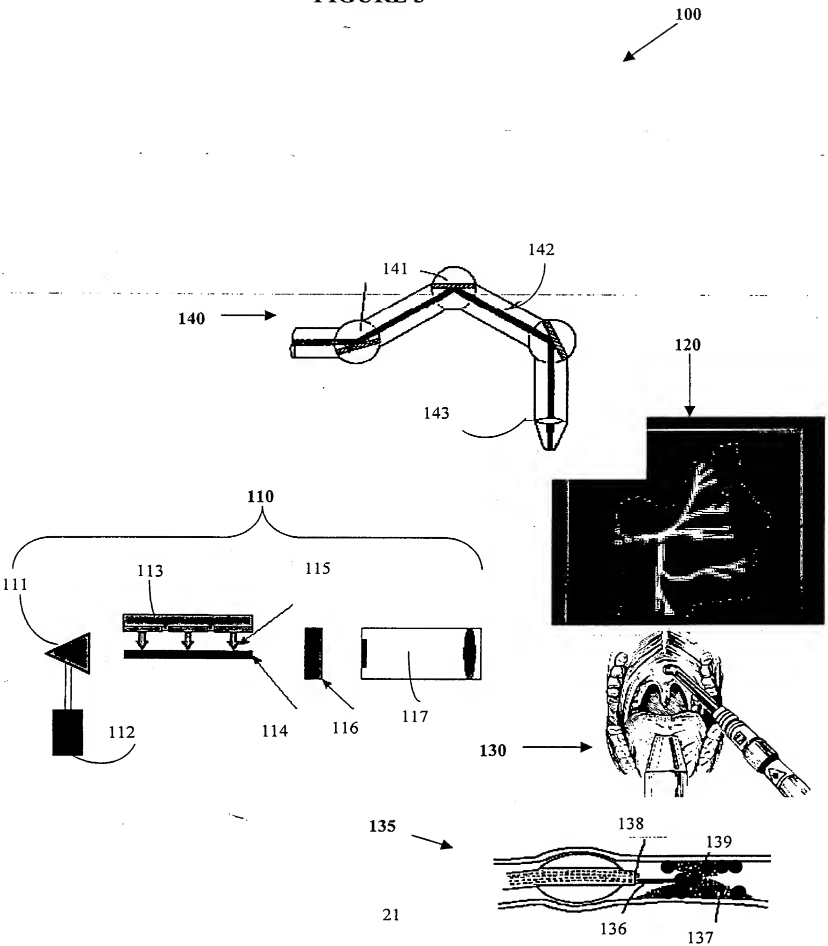

100
142
141
140
120
143
110
113
115
111
112
114
116
117
130
135
138
139
136
137

FIGURE 4

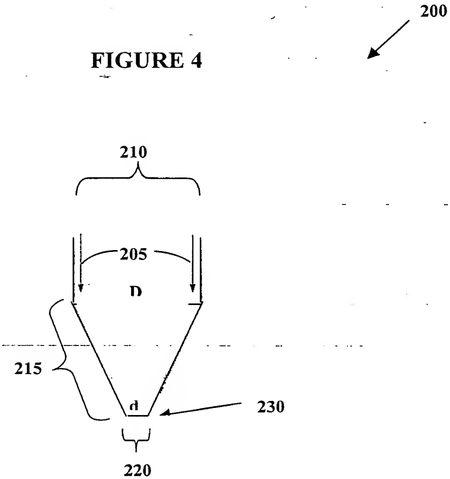
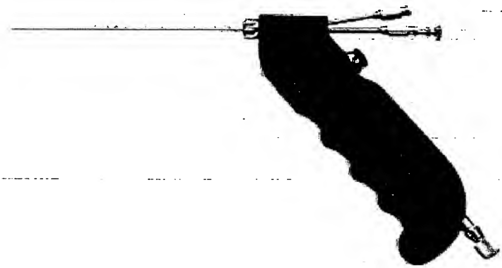


FIGURE 5



A

B